



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,061	08/24/2005	Philippe Coszach	67219-001	7453
26096 7590 05/02/2007 CARLSON, GASKEY & OLDS, P.C. 400 WEST MAPLE ROAD SUITE 350 BIRMINGHAM, MI 48009			EXAMINER TOSCANO, ALICIA	
			ART UNIT 1712	PAPER NUMBER
			MAIL DATE 05/02/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/523,061	<b>Applicant(s)</b> COSZACH ET AL.	
	<b>Examiner</b> Alicia M. Toscano	<b>Art Unit</b> 1712	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 August 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/2/05</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Priority***

1. Applicant is advised of possible benefits under 35 U.S.C. 119(a)-(d), wherein an application for patent filed in the United States may be entitled to the benefit of the filing date of a prior application filed in a foreign country.
2. Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a certified English translation of the foreign application must be submitted in reply to this action. 37 CFR 41.154(b) and 41.202(e).

Failure to provide a certified translation may result in no benefit being accorded for the non-English application.

After submission of the certified translation the Van Gansberghe reference below will be a 102(a) (based on publ. PCT date 8/27/01) date.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1712

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
3. Claims 1-10, 13-32, 35-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gruber (US 6326458) in view of Van Gansberghe (US 6800767).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Gruber discloses processes for the manufacture of lactide and lactide polymers. Said process includes evaporation of free water to form lactide oligomers having a molecular mass of around 400-2500 g/mol (Column 6 Lines 5-29). The total acidity and optical purity is not explicitly disclosed but since these properties depend on the MW and amount of water evaporated the Examiner finds these properties to be inherently met. The lactic acid is then depolymerized (Column 7 Line 27) to form a crude lactide vapor phase (Column 7 line 52) and a solution comprising the impurities and oligomers (Column 7 Lines 39-42). The crude lactide may be condensed (Column 7 Line 59) leaving impurities in the vapor and further polymerized (abstract)

Gruber does not disclose the use of melt crystallization after condensing the crude lactide monomer prior to polymerization nor the aqueous treatment steps further required by Claims 1-4.

Van Gansberghe discloses methods for purifying cyclic ethers. The method of Van Gansberghe includes (a) extractive and controlled crystallization of the raw lactide, (b) separation of the crystals and (c) drying (abstract). Said method also includes melt crystallization after the drying step (abstract), or before the extractive step (Ex 2). Said method is disclosed provide a very high quality of lactide with high mass yield and minimum energy consumption (Column 2 Lines 52-53).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in Gruber the method steps of extraction, crystallization, separation,

Art Unit: 1712

drying and melt crystallization, as taught by Van Gansberghe, in order to obtain a high purity lactide monomer.

Gruber and Van Gansberghe thusly meet the limitations of Claims 1-4. The starting composition of Gruber may be lactic acid, esters of lactic acid and mixtures thereof (Column 4 Lines 45-46), meeting the requirements of Claims 5, 6, 15, 16, 21, 22 and 27-28. The crude lactide is inherently enriched in prepurified lactide fractions when the prepurified product is recycled. Recycling at various points of the purification of the lactide product is disclosed in Column Fig 2 of Gruber and Column 3 Line 37, Column 3 Lines 64-65 and Column 8 Line 12, as required by Claims 7, 8, 13, 17, 18, 23, 24, 29, 30, 35 and 38-43. Examiner finds that the content of D-lactide formed during the process would inherently be controlled by polymerizing the prepurified lactide since the process requirements have been met, as required by Claims 19, 25, 31 and 44-47. Examiner also finds the water content, lactide content, lactic acid oligomer content and meso-lactide content of Claims 20, 26, 32 and 48-52 to be inherent since the purification process steps have been met.

4. Claims 11-12, 33-34 and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gruber and Van Gansberghe in view of O'Brien (US 5521278)

Gruber and Van Gansberghe include elements of the invention as discussed above. Gruber and Van Gansberghe include polymerizing the lactide monomer after purification however Gruber and Van Gansberghe do not disclose the polymerization steps necessary for polymerization.

Art Unit: 1712

O'Brien discloses the manufacture and polymerization of lactide. The polymerization steps include addition of a catalyst (Column 9 line 64-Column 10 Line 19), inherently forming a mixture since one would blend the catalyst and lactide to form a uniform mixture prior to polymerization in order for the reaction to have high yield, and then further polymerizing in an extruder (Column 10 Lines 40-41). The initiation step (b) requires initiation via addition of optional comonomers and the like. Since the addition of said monomers is optional, step (b) does not necessitate any further steps other than the addition of a catalyst and the polymerization in an extruder, as discussed above. Said method results in high polymer yield and low polymerization time (Column 10 Lines 20-23).

It would have been obvious to one of ordinary skill in the art at the time of the invention to include in Gruber and Van Gansberghe the use of a polymerization catalyst and extruder, as taught by O'Brien, in order to reduce the polymerization time whilst obtaining high polymer conversion. Thusly, the limitations of Claims 11-12, 33-34 and 36-37 are met.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alicia M. Toscano whose telephone number is 571-272-2451. The examiner can normally be reached on Monday to Friday 8:30 AM to 5 PM.

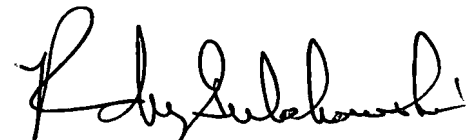
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on 571-272-1302. The fax phone

Art Unit: 1712

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AMT



RANDY GULAKOWSKI  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1700